

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Bimeda Biologicals, Inc.
USDA Vet Biologics Establishment Number	290
Product Code	7905.01
True Name	Mannheimia Haemolytica Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Pro-Bac 2 - No distributor specified
Date of Compilation Summary	February 25, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

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Study Type	Efficacy
Pertaining to	Mannheimia Haemolytica A6
Study Purpose	Efficacy against Mannheimia Haemolytica A6
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	July 19, 1999

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Study Type	Efficacy
Pertaining to	Mannheimia Haemolytica
Study Purpose	Efficacy against respiratory disease due to Mannheimia
-	Haemolytica A1
<b>Product Administration</b>	
Study Animals	
<b>Challenge Description</b>	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 20, 1982

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate Safety under field conditions
<b>Product Administration</b>	
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	October 18, 1999

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